zimmer
dental

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510k No.:

Page No.: A5-1

K101880

Traditional 510(k)
PRE-MARKET NOTIFICATION 510(k)

510(k) SUMMARY (21CFR807.92(a))

1. Submitter's Information:

OCT 1 2010

Name: Zimmer Dental Inc.

Address: 1900 Aston Ave.
Carlsbad, CA 92008

Phone: 760-929-4300

Contact: Melissa Burbage

Date Prepared: June 29, 2010

2. Device Name:
Tapered Screw-Vent® T Implant and *Tapered Screw-Vent® P Implant*

Device Classification Name: Endosseous Dental Implant

2. Predicate Device(s):
   a. Zimmer Dental Tapered Screw-Vent® Implant System
      i. 510(k) Numbers: K011028 / K953101 / K013227 / K061410 / K072589
   b. NobelReplace Tapered Conical Connection
      i. 510(k) Number: K062566
   c. Spline X Implant
      i. 510(k) Number: K962576

4. Device Description:

The *Tapered Screw-Vent® T Implant* is an endosseous dental implant. The implant is composed of titanium alloy. The implant section is designed for ease of implantation and with greater surface area for osseointegration. The implant section surface is treated to facilitate osseointegration. In addition, the implant section is tapered with triple-lead threads.

The *Tapered Screw-Vent® P Implant* is an endosseous dental implant. The implant is composed of titanium alloy and Cancellous-Structured Titanium (CSTi) coating. The implant section is designed for ease of implantation and

with greater surface area for osseointegration. The CSTi coating is designed to allow for bone ingrowth. The implant section surface is treated to facilitate osseointegration. In addition, the implant section is tapered with triple-lead threads.

5. Indications for Use:

The Tapered Screw-Vent® T Implants are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.

The Tapered Screw-Vent® P Implants are designed for use in the maxilla or mandible for loading after a conventional healing period. Implants may be used to replace one or more missing teeth.

6. Device Comparison:

The Tapered Screw-Vent® T Implant is the same as the predicate Tapered Screw-Vent Implant in the implant/abutment connection, implant body design, materials, and manufacturing. This device has been modified to add the MTX texture to the top of the implant and add small grooves on the implant collar similar to the predicate NobelReplace Tapered implant. The new device will feature hydroxylapatite coating, hydroxylapatite coating with additional Zimmer Dental MP-1® processing, or MTX surface equivalent to existing Zimmer Dental implants. The new implant will be offered in 4.7mm and 6.0mm diameters.

The Tapered Screw-Vent® P implant is the same as the predicate Tapered Screw-Vent® implant in the implant/abutment connection, general implant body design, materials, and manufacturing. The modifications to this device include addition of MTX texture to the top of the implant and the addition of small grooves to the implant collar similar to the predicate NobelReplace Tapered implant. Another modification includes a porous surface created using Cancellous-Structured Titanium (CSTi). This is the same porous surface on the predicate Spline X implant (K962576). The new implant will be offered in 4.7mm and 6.0mm diameters.

7. Basis for Substantial Equivalence:

The new devices are substantially equivalent to the predicate devices, the indications for Tapered Screw-Vent® T Implant are the same as the Tapered Screw-Vent Implant and the indications for the Tapered Screw-Vent® P implant have been reduced and only have indications for use in the maxilla or mandible for loading after a conventional healing period. The new devices have the

same technological characteristics as the previously cleared predicated devices, and it can be demonstrated that the devices are as safe and effective as the predicate devices. The new devices do not raise any different questions regarding safety and effectiveness as compared to the predicate devices. The Tapered Screw-Vent® T Implant and Tapered Screw-Vent® P Implant, as designed and manufactured, is as safe and effective as the predicate devices and therefore determined substantially equivalent to the referenced predicate devices.

7.1 Non-clinical test summary:

The new devices have been subjected to bench testing to determine conformance to performance specifications and requirements taking account of its intended use as a dental implant system and following all indications set out in FDA Document "Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments".

Functional laboratory testing preformed in foreseeable operating conditions showed correct operation of the device per its intended use.

7.2 Clinical test summary:

No clinical studies were conducted to evaluate the performance of this device.

8. Conclusion:

We believe that the Tapered Screw-Vent® T Implant and Tapered Screw-Vent® P Implant constitute a safe, reliable and effective dental implant, meeting all the declared requirements of the intended use. The devices present no new adverse health effects or safety risks to patients when used as intended.

We conclude that the new devices are safe and effective for the indications for use, and based on the information included in this submission, we believe that substantial equivalence of the proposed devices with the legally marketed predicate devices may be established.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 1 2010

Ms. Melissa Burbage
Regulatory Affairs Manager
Zimmer Dental Incorporated
1900 Aston Avenue
Carlsbad, California 92008-7308

Re: K101880
Trade/Device Name: Tapered Screw-Vent® T Implant and Tapered Screw-Vent® P Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: September 3, 2010
Received: September 14, 2010

Dear Ms. Burbage:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

zimmer dental

Indications for Use

510(k) Number (if known): K101880

Device Name: *Tapered Screw-Vent® T Implant* and
Tapered Screw-Vent® P Implant

Indications For Use:

The Tapered Screw-Vent® T Implants are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.

The Tapered Screw-Vent® P Implants are designed for use in the maxilla or mandible for loading after a conventional healing period. Implants may be used to replace one or more missing teeth.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101880